



## Background

The Federation notes that s 10 of the *National Health and Medical Research Council Act* requires that the human research guidelines for the conduct of medical research involving humans must be “issued precisely as developed by the Australian Health Ethics Committee” (AHEC). AHEC discharged its responsibility by developing and publishing *Ethical guidelines on Assisted Reproductive Technology* (1996). These Guidelines were revised in 2004 to take account of the provisions of the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning Act 2002* (PHC Act). It is the 2004 NHMRC’s *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* which the present Draft, on which submissions are sought, seeks to replace.

The Draft seeks to incorporate the new legislated permissions as to the use of human embryos and other human tissue effected by the passage in 2006 of the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Amendment Act). That legislation was a consequence of the Lockhart Committee Review of the 2002 Acts.

## Introduction

The Association wishes to address two matters:

- the new definition of human embryo provided in the Amendment Act; and
- the practices previously prohibited by the PHC Act and now permitted under licence by the Amendment Act.

### 1. Definition of the human embryo

The Lockhart Review Committee’s *Issues Paper*<sup>1</sup> provided the accepted definitions of a human embryo and a human embryo clone respectively as in the 2002 legislation:

#### “Human embryo

A live embryo that has a human genome or an altered human genome and has been developing for less than eight weeks since the development of two pronuclei or the initiation of its development by any other means not including any period when its development was suspended for any reason. [*PHOC Act* s 8(1); *RIHE Act* s 7(1)]

#### “Human embryo clone

Advances in cell biology have allowed embryonic development to be started by injecting a cell nucleus extracted from any cell in the body into an egg cell from which the nucleus has been removed (nuclear transfer). **This is the basis of cloning technologies .....** This part of the definition therefore means that **once a cell is created (by nuclear transfer or any other means) that has the same potential to continue development as a cell formed by fertilisation of a human egg and a human sperm, it is included in the definition of a human embryo.**<sup>2</sup> (emphasis added)

Despite this acknowledgement the Lockhart Committee clearly solicited submissions which would displace those very definitions. Its *Issues Paper* was so phrased that it positively invited dissatisfaction with any restraints currently imposed by these two Acts. For example, it queried:

<sup>1</sup> *Issues Paper: Outline of existing legislation and issues for public consultation*. August 2005.

<sup>2</sup> *Issues Paper* pp 5-10.

- whether the definitions of ‘human embryo and ‘human embryo clone’ [in the legislation] were clear and unambiguous; and whether these definitions appropriately reflected community standards;<sup>3</sup>; and
- whether legislative restrictions had hampered stem cell researchers.<sup>4</sup>

In this context, the *human embryo* was described as “*capable of becoming* a human being”<sup>5</sup>, a statement undeniably problematic and argumentative, essentially defying both sound scientific opinion and common sense yet offering no other definition of the *human embryo* to which submissions might be addressed.

A clear indication of propensity to a radical change in the definition of *human embryo* is given in the *Introduction* to the *Lockhart Reports* presented to Parliament in December 2006:

However, the Committee was concerned to hear that this provision [*ie the prohibition on creation of an embryo by fertilisation other than in an ART treatment*], combined with the current definition of a human embryo as starting from the appearance of two pronuclei — a very early stage in fertilisation before the male and female genetic material combine — has had the apparently unintended consequence [**Note 1**] of impeding valuable research and clinical practice in ART clinics.

.....  
 Adopting an independently developed definition [**Note 2**] of a human embryo to a slightly later stage in the fertilisation process (the first cell division) would allow much of the research described above to occur without falling outside the scope of the RIHE Act. [**Note 3**] This change would also maintain a very broad definition of an embryo, in line with all the community views expressed during the reviews, including that a new and unique genetic entity is formed only after the genetic material from the male and female pronuclei combine. [**Note 4**] This stage is known as ‘syngamy’ and occurs about one to three hours before the first cell division (cleavage).

.....  
 To achieve this change, the Committee has recommended that the definition of a human embryo created by fertilisation of a human egg by a human sperm should include the fertilised egg from the first mitotic cell division (cleavage). In addition, the current prohibition of the creation of hybrid embryos has prevented the use of a standard test for sperm maturity by experimental fertilisation of animal eggs. The Committee has therefore also recommended that hybrid fertilisation should be permitted, under licence, up to, but not including, the first cell division.<sup>6</sup>

#### Notes

Note 1. The bland assumption that these consequences were “apparently unintended” is neither explained nor justified.

Note 2. This “independent definition of a human embryo” is referenced in a footnote of the *Lockhart Reports* to an *NHMRC Discussion Paper*.<sup>7</sup>

Note 3. “without falling outside the scope of the RIHE Act” is a strange way of expressing the legal consequences of such a definition of the ‘human embryo’. What clearly is meant is that the RIHE Act would not apply to experimentation on these human entities once they have been excluded by a new definition of *human embryo*

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<sup>3</sup> *Issues Paper* p12.

<sup>4</sup> *Ibid* p15.

<sup>5</sup> *Id.*

<sup>6</sup> Lockhart Legislation Review Committee: *Reports*. December 2005, p xv.

<sup>7</sup> NHMRC Discussion Paper: *Human Embryo – a Biological Definition*, NHMRC, Canberra (January 2006).

Note 4 It is the accepted fact that fertilisation is complete when the chromosomes of the sperm and the egg combine to form the zygote which is a genetically unique individual. Some 1-3 hours later the zygote will undergo the first cleavage division. Yet the Lockhart Committee abandoned the “commonly accepted view” and went for a later stage in the developmental process, the first mitotic cell division.

The Lockhart Committee also emphasised the emergence of new methods of embryo production eg pronuclear transplantation, parthenogenesis, parenting by persons of the same gender.<sup>8</sup> The NHMRC *Discussion Paper* further includes an estimate of the developmental potential of each type of human entity produced by each of the listed methods. In respect of some of these techniques, it is conceded that the resultant embryos can be deliberately prevented from development past a certain stage; for example, the experimental procedure may include effecting a genetic alteration designed to remove the potential for implantation. The Lockhart Committee obviously adopted a proposition of the NHMRC *Discussion Paper* that a “more productive approach to the development of a biological definition of human may be one that does include a reference to a specific developmental point, but in the context of the potential for continued development”.<sup>9</sup>

The Lockhart Committee concluded that a new definition of **human embryo** would best serve research work on early embryos (Recommendation 28). Moreover, the recommended redefinition imposed a development test on any embryo, however created, whether by fertilisation or by somatic cell nuclear transfer, in order to determine whether an embryo would be included in the legislative definition of human embryo and therefore subject to legislative regulation.

#### **Recommendation 28 - Definition of a human embryo**

A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either:

- (a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
- (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and has not yet reached 8 weeks of development since the first mitotic division.<sup>10</sup>

The defining criterion in para (a) is wrong because an embryo created by the combination of egg and sperm is a distinct genetic living entity (zygote) well before cell division can be detected. This definition contains

..... serious flaws which will impede effective regulation of the research to which they refer.  
 .... The basic biological point that requires emphasis is that the placement in time of any developmental point is entirely at the mercy of the technology which is available at the time to **recognise** when that point has been attained. Inevitably, the time of recognition will move closer to the actual time of occurrence of the event as science advances. The *Discussion Paper* acknowledges the divergence between the occurrence and its recognition in 2.3 in pointing out that: *syngamy can not be visually confirmed on a live entity until the first mitotic division is initiated.*<sup>11</sup> [emphases from the original]

<sup>8</sup> NHMRC (2005) *Discussion Paper*. See Table 1 **Reproductive Techniques** and Appendix 1.

<sup>9</sup> NHMRC *Discussion Paper* p 25.

<sup>10</sup> Lockhart Legislation Review Committee: *Reports*. December 2005, p xxiv.

<sup>11</sup> Peter McCullagh: Submission to the Senate Community Affairs Committee Inquiry into the *Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill 2006* and *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* at pp 2-3.

The second paragraph of the definition of *human embryo* in the two amendment Bills – see below - (and adopted in the 2006 Amendment Act) would permit any number of grotesque experiments which could produce a living new human entity which would be excluded from that definition of *human embryo* and from regulation, either because of a developmental incapacity resulting from the method of producing this entity and/or because of a deliberate disabling of that capacity by genetic manipulation.

#### Amending legislation of 2006

Two Bills presented in 2006 to amend the RIHE and PHC Acts contained the definition as recommended by the Lockhart Reports.

In presenting her Bill (the first in footnote 11) Senator Stott Despoja stated among her aims:

This bill seeks to assist this scientific progress by allowing: regulated use of SCNT for research purposes; .....clarifying the definition of a human embryo; and, reviewing the amended Acts after three years of operation.<sup>12</sup>

This description of the Bill's effect on permissible research involving human embryos is simplistic and seriously misleading, particularly in that it does not appreciate that the definition of *human embryo* if adopted would, far from "clarifying the definition of a human embryo", effectively remove research involving many types of human embryonic entities from legislative regulation.

Senator Patterson, in her Bill (the second Bill in footnote 11), also represented the Lockhart Committee's recommendations as "an effective continuation of national legislation imposing prohibitions on human reproductive cloning and some other ART practices, as well as strict control and monitoring, under licence, of human embryo research."<sup>13</sup> Senator Patterson, whose Bill ultimately displaced that of Senator Stott Despoja, also failed to realise that, as a result of the redefinition of the human embryo included in the Bill's provisions, the legislation if successful would be powerless to control foreseeable and increasingly significant areas of human embryo research.

In like vein, the debate during the Second Reading of the Patterson Bill reveals a common misunderstanding of supporters of the Bill that its effect would be to regulate all experimentation of human embryos however they were produced, for example:

The proposed legislation provides the framework and the safeguards that our community requires to ensure that research using human embryos is conducted ethically and safely, and that is why I will be supporting the bill.....This legislation will allow for research that is well regulated, that is safe, that is ethical and that will respect the boundaries that our community expects. Public opinion supports the passage of this bill. I urge senators to reflect that opinion.<sup>14</sup>

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<sup>12</sup> Senator Stott Despoja's introductory speech relating to the exposure draft of her Bill at page 6.

<sup>13</sup> Lockhart Committee Reports p xiv cited in Explanatory Memorandum to Senator Patterson's Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 at p 2.

<sup>14</sup> Senator McLucas, Senate Hansard Tuesday 7 November 2006 p 8-9.

### The NHMRC and the definition of human embryo

Senator Stott Despoja stated that she derived her proposed definition from that produced by a Working Party formed by the National Health and Medical Research Council (NHMRC) Licensing Committee to develop a “biological definition” of the human embryo.<sup>15</sup> Senator Patterson also justified the same redefinition in her Bill in terms which were not correct. She claimed that this definition was the “recommended definition” that was “developed by the NHMRC ..... by forming the Biological Definition of Embryo Working Party, comprising three NHMRC Embryo Research Licensing Committee members and three other Australian experts”.<sup>16</sup>

However the NHMRC had not recommended this redefinition. At its 154<sup>th</sup> Session (16-17 September 2004) it is reported that the AHEC had expressed concern at the then current definition in the 2002 *RIHE* and *PHC* Acts. The matter was referred to the Licensing Committee to “do some work on the definition of embryos issue”. The Licensing Committee established a Working Party to address the matter.

While it is the case that the Discussion Paper prepared by the Working Party out-of-session contained a re-working of the definition of the human embryo in the terms contained in the two Amendment Bills and now included in the Amendment Act, the Paper was not expressly recommended by the NHMRC.

Indeed members of the Council said at its 154<sup>th</sup> Session that “it was not the job of the NHMRC to define when life begins”. Subsequently the NHMRC at its 159<sup>th</sup> Session (8-9 December 2005) endorsed distribution of the *Discussion Paper*<sup>17</sup> prepared out-of-session by the Working Party for the promotion of discussion and asked that the Council be advised of any feedback. In March 2006 the NHMRC’s Licensing Committee sponsored a Workshop to further develop the *Discussion Paper* and planned to publish the definition in the peer reviewed literature. Pending the results of peer review the NHMRC had not finalised any recommendation for changing the definition of the *human embryo* as both Senators claimed.

Further, the NHMRC did not advance such a radically different definition of the human embryo in its submission to the Lockhart Committee:

#### **Definition of “human embryo”**

The key definitions in the PHCA and the RIHEA were developed to provide legal clarity in prosecution of the offence provisions, given the high penalties involved. The definition of human embryo was prepared in consultation with governments and experts in all states and territories and was drafted so as to be independent of technological developments. LC (Appendix 3, page 41) states:

*The LC has not experienced any difficulties with the legal definition of “human embryo” and notes that from a legal perspective it works well. However, LC developed guidance at an early stage to clarify “live”, since this is a key element in determining whether embryos are covered by the provisions of the RIHEA and in carrying out the exempt activity of allowing excess ART embryos to succumb (s.10(2)(c)). The LC notes that the definition of “human embryo” is broad in the scientific sense and includes most entities which researchers may wish to study.*<sup>18</sup> [original italics]

<sup>15</sup> Discussion Paper: *Human Embryo – A Biological Definition*. NHMRC January 2006. (hereafter NHMRC *Discussion Paper*)

<sup>16</sup> Explanatory memorandum to the Bill, Schedule 1, item 3.

<sup>17</sup> NHMRC *Discussion Paper*, see footnote 5.

<sup>18</sup> National Health and Medical Research Council Submission to the Senate Community Affairs Legislation Review Committee, September 2005, p 11.

However, the NHMRC's submission then foreshadowed possible changes in approaches to defining the human embryo, citing comment provided by AHEC:

The concerns of a number of members of AHEC regarding the definition of human embryo in the PHCA and the RIHEA were raised with the Council at its 154th session in September 2004. Council asked the LC to provide it with further advice on this matter. This advice is currently being finalised by a working party of the LC.

AHEC states (Appendix 2, page 28):

*This definition contains, in its opening words, a degree of circularity that has ethical implications for the effectiveness of the Act and the potential developments in ART. To define a human embryo as "a live embryo that..." leaves the central concept of embryo undefined. **If in the development of ART processes, innovative methods are devised to generate entities that resemble or can develop into human beings, but which can be argued are not "embryos", then the legislation can be argued not to regulate their use.***<sup>19</sup> [original italics; bold added]

As the agency responsible for administering the legislation, the NHMRC considers that the definitions in the Acts provide legal clarity. However, the NHMRC also considers that the issue raised by AHEC requires further debate. It is also noted that with the increasingly rapid rate of scientific and technological developments in this area, the biological definitions and ethical frameworks will continue to evolve.

If governments and the community want to continue to prohibit and regulate activities in this field, then it will be important to ensure that definitions have the flexibility to accommodate technological developments, with a process of regular review in the light of such developments.

In view of the open nature of the NHMRC's comments on the definition of *human embryo* the reliance on what was merely a Discussion Paper of an NHMRC Working Party by both Senators for the origins of their proposed legislative redefinition of *human embryo* was unjustified. Senator Stott Despoja stated that inclusion of the primitive streak in the proposed definition "*allows medical science more options in research involving embryos*".<sup>20</sup> This will indeed prove to be the case and more. Unfortunately the redefinition has successfully passed into legislation arguably without a proper appreciation by Federal parliamentarians of the far reaching effects as AHEC explained in the above extract from the NHMRC's submission to the Lockhart Committee. As Dr McCullagh stated:

The incorporation of its definition in legislation in the apparent absence of any widespread debate to inform the Parliament of community attitudes on its specific features could be regarded as inappropriate.<sup>21</sup>

### A way forward

Mindful of the NHMRC's obligations in respect of the amending legislation (to take effect in June 2007) to:

[i]mplement new arrangements to monitor compliance with the *increased scope of the legislation*, and ensure appropriate expertise is available to support the NHMRC Embryo Research Licensing Committee.<sup>22</sup>

<sup>19</sup> *ibid* at pp 11-12.

<sup>20</sup> Draft *Explanatory Memorandum* to the Bill, Schedule 1, Item 1.

<sup>21</sup> See footnote 11 at p 2.

<sup>22</sup> See: <http://www.nhmrc.gov.au/embryos/stemcells/patterson.htm>

the Australian Federation of Right to Life Associations urges the Council to take note of the problems associated with the amended definition of human embryo contained in the 2006 amending legislation. Certain internal inconsistencies in the legislation's treatment of hybrid embryos are addressed briefly in the Appendix.

Notably, the Draft Ethical Guidelines admit the unsatisfactory nature of the redefinition and to overcome its deficiencies suggest that the legislative provisions be 'applied' in such a way that reinstates recognition of the early embryo before the first mitotic cell division as being a *human embryo* and regards any group of human cells capable of reaching the blastocyst stage also as deserving the status of a *human embryo*.<sup>23</sup> While such an application might provide proper protection to all classes of human entities and bring them into the regulatory scheme for licensing, it could be argued that the application could be challenged as not consistent with the provisions of the legislation.

The NHMRC is asked to attend particularly to the strong probability that large classes of human embryonic entities will be beyond the reach of the regulatory regime when the amended legislation commences. While the Lockhart Committee might well have intended this outcome,<sup>24</sup> it would not seem to have been the intention of the NHMRC's work nor the understanding of the legislators. To clarify the matter, the Council should request the Minister to propose an amendment to the Parliament which would settle the definition as the Draft Guidelines intimate in its proposal for applying the amended definition

## **2. Practices previously prohibited by the PHC Act and now permitted under licence by the Amendment Act.**

The Federation has examined the *Draft Guidelines* in the light of its own governing principle, that is, to offer a voice for vulnerable human beings, from their earliest beginning until natural death. It must be said at the outset that it is disappointing that the Draft Guidelines, which identify among the "relevant ethical dimensions of ART" the recognition of "the basic human goods at stake" and "the importance of an ethical framework for the use of gametes and embryos in clinical practice, training and research"<sup>25</sup> make no reference in its text to those seminal documents which traditionally set relevant international standards.

The ethical principles underlying the *Draft Guidelines*, set out in **Part B** and **Part C** of its text, embrace ironies like the headings:

- **Respect all participants.**<sup>26</sup> Despite stating that procedures must be "respectful of all involved", participants, while including donors of gametes and persons who may be born, exclude those embryos to be destroyed in experimentation.
- **Respect human embryos.**<sup>27</sup> Limitation of the number of embryos to be the objects of experimentation does not constitute respect for them as human subjects.
- **Obtain consent.**<sup>28</sup> The embryos involved in experimentation clearly are not able to consent to their manipulation or destruction; parent(s) should not be able to consent to these procedures in respect of their offspring.

<sup>23</sup> Draft ethical guidelines **Explanation of key terms**: human embryo, at p 70.

<sup>24</sup> Lockhart Legislation Review Committee: *Reports*. December 2005, p xv.

<sup>25</sup> Draft *Ethical Guidelines* p 6.

<sup>26</sup> See paras 5.1 and 15.1.

<sup>27</sup> See paras 5.2 and 15.2.

<sup>28</sup> See paras 5.5 and 15.7.

All of these instances of ‘ethical principles’ are virtually self-contradictory and are little better than sad examples of *Newspeak* which George Orwell would instantly recognise.<sup>29</sup> They are most certainly in conflict with international statements governing ethical practices in medical research on human subjects.

International statements relevant to human rights and the treatment of human subjects in medical practice and experimentation.

The many international statements governing ethical practices in medical research on human subjects demand respect for the dignity and integrity of the human subject:

**A. The Nuremberg Code: Directives for Human Experimentation<sup>30</sup>**

1. The voluntary consent of the human subject is absolutely essential.  
.....
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

**B. Helsinki Declaration<sup>31</sup>**

**Introduction**  
.....

The Declaration of Geneva of the World Medical Assembly binds the physician with the words: "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

**I. Basic principles**  
.....

- (6) The right of the research subject to safeguard his or her integrity must always be respected

**III. Non-therapeutic biomedical research involving human subjects (Non-clinical biomedical research)**

- (1) In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.  
.....
- (4) In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

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<sup>29</sup> 1948.

<sup>30</sup> "Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.

<sup>31</sup> Adopted by the 18th World Medical Assembly Helsinki, Finland, June 1964 and amended by the 29th World Medical Assembly Tokyo, Japan, October, 1975, 35th World Medical Assembly Venice, Italy, October 1983' and the 41st World Medical Assembly Hong Kong, September 1989

## C. Statements of the United Nations General Assembly concerning the rights of children

### 1. Universal Declaration of Human Rights (1948)<sup>32</sup>

**Article 3 :** Everyone has the right to life, liberty and security of person."

**Article 25(2):** Motherhood and Childhood are entitled to special care and assistance."

### 2. Declaration of the Rights of the Child (1959)<sup>33</sup>

This document expands and amplifies the theme of **Article 25(2)** of the *Universal Declaration of Human Rights*.

#### **Preamble**

Whereas the peoples of the United Nations have, in the Charter, reaffirmed their faith in fundamental human rights and in the dignity and worth of the human person, and have determined to promote social progress and better standards of life in larger freedom,

Whereas the United Nations has, in the Universal Declaration of Human Rights, proclaimed that everyone is entitled to all the rights and freedoms set forth therein, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status,

**Whereas the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth,**

### 3. International Covenant on Civil and Political Rights (1966)<sup>34</sup>

#### **Article 6**

1. Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life."

### 4. Convention on the Rights of the Child (1989)<sup>35</sup>

Convinced that an international convention on the rights of the child, as a standard-setting accomplishment of the United Nations in the field of human rights, would make a positive contribution to protecting children's rights and ensuring their well-being,

**Bearing in mind that 1989 marks the thirtieth anniversary of the *Declaration of the Rights of the Child* and the tenth anniversary of the International Year of the Child,.."**  
(bold added)

[There follows an enumeration of specifics rights to be afforded to the child]

## D. Resolution on cloning of the United Nations General Assembly

<sup>32</sup> Adopted and proclaimed by General Assembly resolution 217 A (III) of **10 December 1948**. The Declaration is a non-binding statement of principles which later developed into various Conventions for signature by member States of the United Nations.

<sup>33</sup> This document is a non-binding resolution of the United Nations General Assembly. It would be elaborated for ratification as the *Convention on the Rights of the Child*.

<sup>34</sup> Entry into force generally (except Article 41): 23 March 1976. Entry into force for Australia (except Article 41): 13 November 1980. Article 41 came into force generally on 28 March 1979 and for Australia on 28 January 1993

<sup>35</sup> Adopted by the UN General Assembly on the thirtieth anniversary of the *Declaration of the Rights of the Child*, 20 November 1989. This document is a binding treaty to which 176 nations have become "states parties".

The Federation notes that it brought to the attention of the Senate Community Affairs Legislation Committee considering the amendment Bills of Senators Stott Despoja and Patterson the recent United Nations ban on all forms of human cloning. On 8 March 2005 the United Nations General Assembly approved a declaration calling on UN Member States to ban all forms of human cloning, including cloning for medical treatment, as incompatible with human dignity and the protection of human life. The Assembly adopted the text to be known as the *United Nations Declaration on Human Cloning*. The Declaration calls on member States to take a number of steps, including:

- adopting all measures necessary to adequately protect human life in the application of life sciences;
- prohibiting all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;
- adopting the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity;
- taking measures to prevent the exploitation of women in the application of life sciences;
- adopting and implementing without delay national legislation to protect adequately human life and to prevent the exploitation of women.

In a pre-emptive strike designed to denigrate this UN statement the Lockhart *Issues Paper* commented that 35 countries did not support the UN resolution.<sup>36</sup> It is surprising that the *Paper* highlighted dissent rather than providing the full voting record: 84 member States in favour, 34 against, 37 abstaining, with 36 absent (it is a well-known tenet of international law that States who abstain from voting on a resolution are taken not to have vigorous objection to a resolution).

The Federation embraces these principles and remains implacably opposed to all experimentation on human embryos which involves their destruction without demonstrable benefit to the embryo as a human subject. This includes both the experimental protocols involving excess embryos from ART programs and those practices previously prohibited by the *PHC Act 2002* and (from June 2007) to be allowed under licence include:

- creating a human embryo other than by fertilisation, or developing such an embryo [s 22];
- creating or developing a human embryo containing genetic material provided by more than 2 persons [s 23];
- using precursor cells from a human embryo or a human foetus to create a human embryo, or developing such an embryo [s23A];
- creating a hybrid embryo [s23B – Note: a licence to create or develop a hybrid embryo can only be issued under section 21 of the RIHE Act 2002 and only for prescribed purposes].

All such practices are ethically bankrupt in that they treat human subjects as experimental material. Particularly distasteful is that activity licensable under s 23A of the *Prohibition of Human Cloning for Reproduction Act 2002* (as amended in 2006):

**23A Offence—using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo**

A person commits an offence if:

- (a) the person uses precursor cells taken from a human embryo or a human fetus, intending to create a human embryo, or intentionally develops an embryo so created; and

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<sup>36</sup> Issues Paper: Outline of existing legislation and issues for public consultation. August 2005 Lockhart Review of Australia's *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* (hereafter referred to as the *Issues Paper*), page 25.

- (b) the person engages in activities mentioned in paragraph (a) without being authorised by a licence, and the person knows or is reckless as to that fact.

To produce offspring of a miscarried or aborted female child is redolent of some Brave New World where all sensibilities are deadened and respect for human beings abandoned.

The Australian Federation of Right to Life Associations appreciates that the legislation will inevitably involve other human subjects eg women, whether involved in an ART program or not, who will be induced to donate eggs for the purpose of creating human embryonic entities (ie, putting aside the exclusionary terms of the legislated redefinition, human embryos). Issues such as informed consent, the dependent status of many egg donors, commercialisation and profit from research on human embryos are addressed in the current *Guidelines* and the Federation has made submissions on these and other issues previously.<sup>37</sup>

The Federation declines to make any further comment on practices which denigrate the dignity of human life at all its stages and where legislation removes from embryos the protection due to their humanity. The Lockhart Committee recommended, and the amending legislation insists on maintaining the prohibition of human reproductive cloning by which is meant bringing a clone to birth. The Federation submits that all cloning is reproductive as it creates a new entity with a human genome; deliberately cutting short its development does not change its nature. The newly permitted practices under licence are based on bad principle and poor reasoning.

### **Conclusion**

The Australian Federation of Right to Life Associations asks the NHMRC to request the Minister to propose an amendment to the Parliament which would clarify the definition of *human embryo* so that it (a) protects the embryo from its first beginnings; and (b) that all embryos, no matter how produced, are brought into the scope of legislative regulation.

Nonetheless, the Federation opposes all experimentation on human embryos which destroys them; such procedures ignore the dignity and respect due to all human subjects.

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<sup>37</sup> Submission to the National Health and Medical Research Council of its review of the Council's *Ethical guidelines on assisted reproductive technology* (1996) in November 2001.  
 Submission to the National Health and Medical Research Council on the Review of the National Statement on Ethical Conduct in Research Involving Humans (1999) First consultation draft. Australian Federation of Right to Life Associations, March 2005.  
 Submission to the National Health and Medical Research Council on the Draft of the National Statement on Ethical Conduct in Human Research. Second consultation. Australian Federation of Right to Life Associations, March 2006.